Maryland Pharmacy Program

Growth Hormone (GH) Prior-Authorization Request

Initiation and Continuation of GH Therapy- Approval of the Non-Preferred Drug

Phone: 800-492-5231 Option 3 or 410-767-1455

Fax to: 410-333-5398 (Incomplete forms will be returned)

Section I- Patient Information

Patient name: _____ MA ID#:_____

DOB: _____Patient phone#: (_____) _____ - _____Other insurance:_____

Section II- Prescriber Statement of Medical Necessity/Drug/Clinical Information

Prescriber: _____ Phone #: (_____) _____ - _____

Address: _____ Fax #: (_____) _____ - _____

Endocrinologist or nephrologist Yes____ No _____ Estimated length of GH therapy: _____

I certify that this treatment is medically necessary and meets the guidelines of the Maryland Medicaid Program. I will be supervising the patient's treatment. Supporting documentation is available in the patient record.

_____Date:_____ License #: _____

Prescriber's Signature

1. Initial request ___Renewal __ Drug/Dosage frequency:_____

The Preferred drugs are **Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, and Tev-Tropin.** Complete Section III if request is for a non-preferred drug.

2. Patient's weight: _____lbs/kg- Date patient last seen: _____
   Primary diagnosis: _____(Do not use ICD-9)
3. Confirmed by a board certified endocrinologist or nephrologist? Yes _____ No_____
4. Diagnostic tests: GH deficiency (GHD) confirmed with provocative testing and IGF-1 level for both children and adults with GHD:
   - ❑ Adult with childhood onset GHD or with additional pituitary hormone deficits- 1 stimulating test required
   - ❑ Adult and children with suspected GHD with no other pituitary hormone deficits- at least 2 stimulating tests required

     Test 1: type_____Results: _____ng/ml- Normal range: _____Test Date: _____

     Test 2: type_____Results: _____ng/ml- Normal range: _____Test Date: _____

     As provocative testing, ITT is required unless contraindicated. If contraindicated (seizures, CAD, abnormal EKG with history of IHD or CVD, and not advised for those>age 60), documentation must be provided and an alternative test result (arginine, glucagon, GH releasing hormone, L-dopa and combination of these agents, excluding clonidine) may be substituted. For patients with Chronic Renal Insufficiency (CRI) on dialysis, only an IGF-1 level is required.

     Insulin-Like Growth Factor-1 (IGF-1) level (required annually): _____ng/ml Date: _____

     Is there a contraindication to Insulin Tolerance Test (ITT)? Yes ___ No ____

     If yes, state reason:_____

   If request is for adult GH therapy, skip items 5&6 below.
5. If request is for a child, is the patient's height less than the 3rd percentile, or if **2.00** standard deviation (SD)or more below mean height for chronological age? Yes ____ No _____ Height: ____ Percentile _____Attach copy of growth chart.
6. Bone age: _____ ; Chronological age:_____ Date of most recent radiology report:_____
   Is bone age < chronological age <=- 16 yrs (boys);<= 14 yrs (girls)? Yes_____ No_____ Has bone fused? Yes____ No____
7. For adults requiring GH therapy, provide results of bone density test, if done- T score _____on DEXA testing or ___ SD by WHO
8. Has the patient been screened for intracranial malignancy/tumor: Yes ___ No ___ (If no, request will be denied)
   If a h/o of malignancy exists, has it been free of recurrence for at least the past 6 months? Yes ___ No ___No malignancy_____
9. Does the patient have any of the following contraindications? If any of these apply, request will be denied.
   ___Pregnancy; ___ Proliferative/preproliferative diabetic retinopathy; __ Pseudotumor cerebri or benign intracranial HTS___
   ___Status/post renal transplantation; ___Untreated chronic disease causing growth failure (i.e. hypothyroidism, liver disease, etc.)
   Explain: _____
10. Is patient on: Corticotropin? Yes__No__ Systemic glucocorticoids? Yes__No__; Antitumor chemotherapy? Yes__ No___
11. Results of thyroid function tests (required every 6 months): _____
12. List any other pertinent lab tests done with results:_____

Section III- Prior-Auth of Non-Preferred Drugs-

If a preferred drug is selected, skip this Section. The non-preferred drugs are: **Genotropin, Serostim, Humatrope, and Zorbtive.** These products are synthetic somatropin of recombinant DNA origin, considered therapeutically equivalent to endogenous growth hormones and therefore interchangeable based on their international unit dosing equivalency. They vary in dosage strengths and forms, added preservatives, length of stability after mixing, and FDA-approved indications. Prescribers should only use a non-preferred drug when absolutely necessary. Patients who have been receiving a preferred drug that has become non-preferred do **not** need to be switched to an agent on the preferred drug list Serostim has the approved indication for AIDS wasting syndrome and requires completion of a separate Prior Authorization form.

If prescribers must use a non-preferred drug for a patient's initial growth hormone therapy, please provide valid reasons for selecting the non-preferred drug: _____

Maryland Pharmacy Program- Division of Pharmacy Services

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Section IV- Children GH Therapy Evaluation- (If adult, skip this section and complete Section V).

Diagnoses: Patient must have one of the following primary indications listed below. Please check applicable diagnosis:

- ❑ Documented growth hormone deficiency
- ❑ Turner Syndrome- Is diagnosis confirmed by karyotyping? Yes ___ No ___
- ❑ Prader Willi Syndrome- Is diagnosis confirmed by appropriate chromosomal testing? Yes___No____ Submit documentation of chromosomal abnormality. No need for provocative testing. Reassess need for continued long-term therapy in obese patients and those with severe respiratory&vascular complications.
- ❑ Growth deficiency due to chronic/irreversible renal insufficiency- Is patient on dialysis? Yes__ No __ If no, request will be denied.
- ❑ If none of the above, explain: _____

Continuation of therapy: Provide the following:

- ❑ Date of last office visit: _____Date when GH therapy was initiated:_____
- ❑ Growth chart (Attach)- Height <25th percentile of normal height for gender? Yes___ No___
- ❑ If goal of 25th percentile of normal height has been achieved, please reassess and provide rationale for patient's continued GH therapy: _____
- ❑ Epiphyses open? Yes ___ No ____ Anticipated length of therapy:_____
- ❑ Height velocity >= 2.5cm/yr over previous untreated rate? Yes____ No___ Height velocity measured over at least 6 months with at least 2 measurements: _____cm per___months.
- ❑ Bone age per radiological report: _____ Date of test: _____Chronological age:_____
- ❑ Normal thyroid function test? Yes___ No____;IGF-1 level: _____ng/ml Test date: _____
- ❑ Based on results of recommended lab tests, thyroid function tests and IGF-1 levels (both initially and at least annually thereafter), is continuation of GH therapy justified? Yes__No__ IGF-1 level: _____ng/ml
- ❑ Comment on GH therapy efficacy, adverse effects, any compliance issues: _____

Section V - Adult Growth Hormone Therapy Evaluation

Diagnoses: Patient must have one of the following primary indications. Check applicable diagnosis:

- ❑ Adult with childhood onset of growth hormone deficiency
- ❑ Adult onset of growth hormone deficiency with no other deficiencies
- ❑ Adult onset of growth hormone deficiency with other pituitary hormone deficiencies

If none of the above, explain: _____

_____

Continuation of therapy: Provide the following:

1. IGF-1 level (within the past 12 months): _____ng/ml Date of test:_____
2. Based on annual evaluation of fasting lipid profile, BUN, fasting glucose, electrolyte levels, bone density testing (recommended after the first year, then every 3 years thereafter), is continuation of GH therapy justified? Yes___ No____ Anticipated length of therapy: _____
3. Comment on GH therapy efficacy, adverse effects, any compliance issues: _____

_____

Internal Use: Clinical PA ☐ **Approved**: _____/_____ **Approval is for 6 months from: _____ to _____**
(Medical necessity for growth hormone therapy must be renewed every 6 months)

☐ **Rejected:** _____/_____ **Patient does not meet criteria.**

PDL PA (Use of Non-Preferred Drug): ☐ **Approved** ☐ **Rejected** -Invalid reason